

Assistant Secretary for Legislation Washington, D.C. 20201

## September 13, 2018

The Honorable Greg Walden Chairman House Committee on Energy and Commerce Rayburn 2125 Washington, D.C. 20515

## Dear Chairman Walden:

Thank you for your letter of November 16, 2017, requesting that the Department of Health and Human Services (HHS or the Department) convene a sector-wide effort to develop a plan of action for creating, deploying, and leveraging bills of materials (BOMs) for health care technologies.

In a prior response to your committee, dated January 18, 2018, we outlined a preliminary plan for undertaking this convening of interested parties, including a timeline for identifying and contacting potential participants who would represent the diverse stakeholders across the sector to solicit interest and availability, as well as steps for organizing and executing a public meeting, followed by publishing a meeting summary (see attached).

We are updating our plans for this important collaboration based on significant progress over the past six months, including collaboration under the Healthcare and Public Health (HPH) Critical Infrastructure Protection (CIP) program's public-private partnership. The HPH CIP in HHS' Office of the Assistant Secretary for Preparedness and Response leads a public and private sector partnership known as the Healthcare Sector Coordinating Council (HSCC). This partnership has expanded its membership in both overall numbers and in the diversity of engaged and collaborative stakeholders, so that it comprises federal and state agencies, medical product manufacturers, healthcare delivery organizations, payers, professional societies, and technology companies. These stakeholders face daily challenges in strengthening the state of cybersecurity in healthcare, and recognize the value of working together to mitigate potential threats – including public-private engagement for BOM efforts. HHS and private sector partners agree that with this evolution the most suitable place to convene BOM efforts is under the HSCC. The HSCC can leverage existing efforts and highly committed and motivated, cross-sector, HHS-partnered task groups for developing a BOM strategy as well as integrating that strategy into a broader cybersecurity risk management strategy for medical device and health IT design, manufacture, and user management.

The Department continues to recognize that having an open and collaborative process for identifying cybersecurity risks and developing solutions can help mitigate some risks. Therefore, our updated plan for convening a meeting of interested parties in a public forum, is as follows:

By July 30, 2018	Announce the software BOM effort work stream to be conducted under the Healthcare Sector Coordinating Council (HSCC) MedTech Cyber Security Risk Management Task Group 1B (see press release at https://healthsectorcouncil.org/health-sector-mobilizes-against-cyber-threats/)
By November 30, 2018	Publish Federal Register notice for public meeting
By January 26, 2019	Publish proposed agenda for the public meeting
February 25, 2019	Hold public meeting (draft deliverables will be vetted in a public setting)
By August 24, 2019	Publish meeting summary to include responses to any recommendations made at the meeting or in the docket for the meeting

We hope that you will find this information helpful, and look forward to continuing to work with you and interested stakeholders to identify meaningful and achievable solutions to cybersecurity risks.

Sincerely,

Matthew D. Bassett

Assistant Secretary for Legislation

Department of Health and Human Services

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cc: The Honorable Frank Pallone, Jr., Ranking Member The Honorable Diana DeGette, Ranking Member Subcommittee on Oversight and Investigations